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2	UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS
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4	IN DE. NEW ENGLAND COMPOUNDING \ MDI NO 12 00410 EDG
5	IN RE: NEW ENGLAND COMPOUNDING ) MDL NO. 13-02419-FDS PHARMACY CASES LITIGATION )
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10	BEFORE: THE HONORABLE JENNIFER C. BOAL
11	DEFORE: INE NONORADLE JENNIFER C. BOAL
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13	MOTION TO QUASH
14	MOTION TO QUASIT
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16	John Joseph Moakley United States Courthouse Courtroom No. 17
17	One Courthouse Way Boston, MA 02210
18	B03 c011, FH1 02210
19	February 6, 2014 10:00 a.m.
20	10.00 a.m.
21	
22	Catherine A. Handel, RPR-CM, CRR
23	Official Court Reporter  John Joseph Moakley United States Courthouse
24	One Courthouse Way, Room 5205  Boston, MA 02210
25	E-mail: hhcatherine2@yahoo.com

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APPEARING TELEPHONICALLY FOR OBJECTORS: Attorneys for Southeast Michigan Surgical Hospital, by KATHRYN J. HUMPHREY, ATTORNEY, and SUSAN ASAN, ATTORNEY, 400 Renaissance Center, Detroit, Michigan 48243-1668; Marks, O'Neill, O'Brien, Doherty & Kelly, P.C., by MICHELLE J. MARZULLO, ATTORNEY, 600 Baltimore Avenue, Suite 305, Townson, Maryland 21204; Fuller, Mitchell, Hood & Stephens, LLC, by HALLEY M. STEPHENS, ATTORNEY, 2565 Barrington Circle, Tallahassee, Florida 32308; Law, Brandmeyer Packer, LLP, by PAUL M. CORSON, ESQ., 245 S. Los Robles Avenue, Suite 600, Pasadena, California 91101. 

## PROCEEDINGS

(The following proceedings were held in open court before the Honorable Jennifer C. Boal, United States Magistrate Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, 1 Courthouse Way, Boston, Massachusetts, on February 6, 2014.)

COURTROOM DEPUTY CLERK YORK: You may be seated.

Today is February 6, 2014. We're on the record in the matter of New England Compounding Pharmacy, Incorporated, Case No. 13-MD-2419.

Will counsel for the plaintiffs' steering committee please identify yourself for the record and all parties after that.

MS. PARKER: Good morning, your Honor. Kristen Johnson Parker of Hagens Berman Sobol Shapiro for the plaintiffs' steering committee.

MR. STRANCH: Good morning, your Honor. Gerard Stranch of Branstetter, Stranch & Jennings on behalf of the plaintiffs' steering committee.

MR. CHALOS: Good morning, your Honor. Mark Chalos on behalf of the plaintiffs.

MR. LIPTON: Marc Lipton, your Honor.

MR. FENNELL: Patrick Fennell from Crandall & Katt for plaintiffs' steering committee.

MR. GASTEL: Ben Gastel from Branstetter, Stranch &

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Jennings for plaintiffs' steering committee.
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               MS. DOUGHERTY: Good morning, your Honor.
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      Dougherty from Janet Jenner & Suggs, on behalf of plaintiffs'
      steering committee.
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               MR. ZAMORA: Good morning, Judge. Mark Zamora.
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              MR. REHNQUIST: Jim Rehnquist, Goodwin Procter, for
 7
      Unifirst.
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               MR. LAUNER: Good morning, your Honor. Josh Launer
      from Goodwin Procter, for defendant Unifirst.
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10
               MS. DORMAN: Good morning, your Honor. Nicole Dorman
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      from Rose Kallor for Liberty Industries.
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              MS. LUCY: Good morning, your Honor. I'm Jeannette
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      Lucy and I represent Travelers Property Casualty Company of
14
      America.
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               MS. KELLY: Good morning, your Honor. Sarah Kelly
      for the St. Thomas entities.
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               MR. COREN: Good morning, your Honor. Michael Coren,
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      co-chair, official creditors' committee. I also am here in an
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      individual capacity representing New Jersey and Ohio victims.
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               MR. NOLAN: Good morning. I'm George Nolan from
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      Nashville and we represent certain plaintiffs.
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               MR. BLUMBERG: Jay Blumberg from the Law Office of
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      Jay Blumberg on behalf of the Premiere defendants.
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               MR. ABELN: Anthony Abeln on behalf of BKC.
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               MR. CONNORS: Matthew Connors, your Honor, on behalf
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      of Ocean State Pain Management.
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               THE COURT: All right. Anyone else in the courtroom
 3
      wish to identify themselves?
               (No response.)
 4
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               THE COURT: All right. I understand we have a number
 6
      of people on the phone as well. So, good morning everyone. I
 7
      appreciate that so many of you are here despite the snowstorm
 8
      yesterday and I completely understand why others of you were
 9
      only able to appear by phone.
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               Because there are individuals on the phone, as we've
11
      done before, if you're speaking, I would just ask if you could
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      pull the microphone towards you and you may stay seated.
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      find that's usually a better way to transmit as loudly as we
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      can over the microphone.
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               If you don't have a microphone -- I believe, Mr.
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      York -- is the microphone at the podium working?
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               COURTROOM DEPUTY CLERK YORK: Yes.
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               THE COURT: I would just ask that you go to the
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      podium if you wish to speak.
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               So, I'm first going to hear the motions to quash
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      filed by Travelers and Liberty and I will hear from those
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      parties first.
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               MS. HUMPHREY: Your Honor, this is Kathy Humphrey on
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      the phone and I just want to bring to the Court's attention
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      that we were aware that people were making introductions, but
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we heard two voices and mostly silence. So, if you would be
kind enough before the arguments start full swing to just do a
sound check for those of us on the phone, we would be
grateful.
         THE COURT: I believe I just -- did you hear when I
-- well, this will be a good check. Did you hear when I asked
people to speak into the microphone?
         MS. HUMPHREY: Yes, we did hear that. You are loud
and clear.
         THE COURT: All right. Well, hopefully, my
suggestion will help you hear going forward, because it didn't
make sense for purposes of the introduction to have everyone
go to a microphone, but hopefully going forward you will be
able to hear everyone.
         So, I will hear from -- is it Travelers first?
         MS. LUCY: I believe so, your Honor.
         Can everyone hear me?
        MS. HUMPHREY: Yes, that's good. Thank you.
        MS. LUCY: Okay. Good. Your Honor, thank you.
         Travelers Property Casualty Insurance Company of
America is a non-party, as the Court knows, to this
litigation. It has been served with a Rule 45 subpoena with
four categories of documents sought.
         We filed a motion to quash the subpoena on the basis
that it is overly broad, seeks the discovery of information
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not reasonably calculated to lead to the discovery of admissible evidence and could be unduly burdensome and onerous. I wanted to take the Court through some of the arguments that my brothers have made on the PSC side as well as our arguments.

As the Court knows, the injuries and deaths that occurred in this lawsuit happened during the timeframe of May 21st, 2012 and September 24th, 2012.

THE COURT: But my understanding is that the PSC -- and as far as I know, these haven't been dismissed in any way -- have made allegations against Liberty that go back to 2005.

MS. LUCY: That may well be, your Honor. We are not privy to everything that's been going on in this lawsuit. We have some of the information, and I am going to address some of that to hopefully narrow the issue for the Court to rule on.

Travelers today -- so, the injuries occurred during that timeframe. Travelers over the timeframe of May 2005, 2006 through November of 2010 at various points in time, not continuously, issued insurance policies to Liberty. These policies covered different things and they're not for all of Liberty's practices, but they're piecemeal policies.

Travelers has produced the one policy that would have been closest in time to the injuries alleged in this lawsuit. So, it's my understanding we've already produced a copy of the

policy and the letter cancelling the policy for the policy period of November 1st, 2010, which was supposed to run November 1st, 2010 through November 1st, 2011. The cancellation notice was sent, I believe, on January 20th, 2011, with the reasons stated and all of the parties, as I understand it, have seen that.

The policy, your Honor, was an occurrence policy. So, it provided coverage if there was an injury or a death that happened during the policy period. That is conceded by the plaintiffs if you look at their memorandum submitted. They've had an opportunity to read it. Quite clearly, there was absolutely no coverage for the claims asserted in this lawsuit even if that policy had not been cancelled.

So, the timeframe of the policy was -- if it stayed fully in effect would have been November to November, 2010 to 2011. It was an occurrence policy, injury policy, and that's the language.

All of the deaths and the injuries in this case, your Honor, not to say it lightly, but those all happened in 2012 and that was really the reason I mentioned it. It has to do with the type of insurance coverage that is mentioned.

Travelers is a non-party, doesn't have any issue other than whether or not there's coverage in this litigation initially, and it's uncontested by Liberty that the cancellation was proper and there was no policy in effect at

the time of the injuries and the deaths alleged.

Plaintiffs have said that, Gee, they would like to see what the other policies were, what's the language in the other policies. So, perhaps they can determine if there would be any argument that they could make that the coverage would be applicable for any type of claims they might conjure or come up with against Liberty, and we initially resisted that saying that there are occurrence policies, but we can certainly understand that the PSC would like to see the insurance policies that Travelers issued during that timeframe. So, they're not continuous. I think there's some here, some there.

So, we would be willing to produce, your Honor, the policies that Travelers issued during that timeframe, I think of 2005, or it could have been 2006, through the 2010, 2011, and that will enable the parties to satisfy themselves as to whether or not there's any potential argument that they might make that Travelers could be on the hook or could have an obligation to provide coverage for the claims that they're asserting or may try to assert in this litigation.

So, my understanding is, your Honor, they're all occurrence. That since the injuries and the deaths didn't occur until long afterwards until 2012, none of them will be applicable, but we are willing to produce those policies.

And in the memorandum they say, Gee, we would like to

see, you know, is that language there. And so, this should satisfy that desire and that goal. So they can know is there any coverage or not.

We think, though, that what they're doing is a much

-- they're going into a fishing expedition and it's much

broader than is there any insurance coverage and they're

attempting to get into areas that have nothing to do with

claims against Liberty and are well beyond that.

The Court probably knows there have been decisions issued in this case. There was a decision November of 2013 talking about 90 subpoenas that PSC issued and the language was viewed overbroad and, in particular, the Court found that the language related was overbroad or ambiguous and kind of struck that language out and said, You don't get to do this, and it has to be calculated to lead to the discovery of admissible evidence.

In addition to that order, it's my understanding that the parties have entered into a mediation conference and that there is a preliminary order issued in the mediation agreement and that under that order -- it's Section H2, Subset A, which talks about informal discovery, what types of discovery are relevant and should be done.

And the insurance policies that they discuss there, if I recall correctly, are policies for the timeframe of 2012-2013, and that is for non-party insurance -- for insurance

policies that could potentially cover any of the parties involved in this litigation as potential defendants or defendant targets.

So, what they're asking in this litigation, it's our position, they're asking for much more than that. They're going beyond the mediation order. They're going beyond the order that talked about narrowing it down, and they're not just looking to coverage. They're trying to get — they're on a fishing expedition attempting to trawl through Travelers' files and see if they can find anything that might be helpful to them.

There is no claim, your Honor, that there was anything ongoing in -- that there was any contamination, I believe, in 2005 or six, or whatever. There's no indication of any policy issue or concern from 2005 through -- we'll go up to 2010. They say -- one of the things they say is, Well, we would like to know about this abrupt, as they call it, cancellation by Travelers of the policy that was issued in November 1 of 2010 and cancelled about two months later, two and a half months later.

So, that's the other argument they make as to why maybe it's relevant that they impose the subpoena on a non-party and try to discover documents. So, they say they're looking for the reasons that that policy was cancelled.

I would submit to the Court that since the policy is

an occurrence policy, that the policy did not apply at the timeframe of the injuries in this lawsuit, that the reasons for Travelers' business decision to cancel that insurance are not really relevant.

THE COURT: But aren't they entitled to probe that?

Isn't it designed or calculated to lead to the discovery of admissible evidence?

MS. LUCY: I suppose, your Honor, you could argue that, and I can see that -- why they would have a desire to see that and anything else, but I would think that, your Honor, all right, if you were to say that maybe they should probe that, that that's all they should be probing, that that's it, that there's no indiction of any prior cancellation or any prior issues. The coverage had been on and off for years.

I understand Liberty has another insurer that may be providing a defense in this case and that, if you will — while I would say that it's not relevant, that I could say perhaps the Court should — if you're going to expand the mediation order, should limit it to what were the reasons or what's the documents related to the — what are the documents related to the cancellation of the policy that was cancelled well — a year — a year before — more than a year before the injuries in this lawsuit.

So, that's what we're suggesting, your Honor. We,

quite frankly, think that that's -- that while there's -- that that would be appropriate, that that would be reasonable, that that should address the issues that they say they have and also prevent us from having to go into an overbroad fishing expedition, digging into our files, trying to see if there's any other possible basis for anything that they might to try to come up with in this litigation, and that that's just not simply -- what they're trying to do is not appropriate discovery. So, those are my suggestions. And thank you very much.

THE COURT: Thank you. All right. Counsel for Liberty.

MS. DORMAN: While Attorney Lucy has touched upon many of the broader points associated with the PSC's subpoena to Travelers, Liberty's concern arises from the way that the subpoena really very much morphed in the process of the meetand-confer process.

When we received the Liberty -- the subpoena directed to Travelers, there were four categories of documents that were related. Travelers objected on the basis that have been just touched upon, but then in January, which, admittedly, was well beyond the 14 days required for filing of a motion to dismiss, we received notice that the PSC was now going full bore after all policy documents and all documentation relating to why this policy was cancelled in November of 2010, two

years before the outbreak and at least five years after
Liberty last did any work at NECC. And the reasons that were
given in this form cancellation notice related to the way that
catalog products were represented in Liberty's catalog
listings in 2010.

For our part, those have absolutely nothing to do with how Liberty constructed or designed clean rooms back in 2005 and 2006 and -- but -- and, you know, I know that the familiar refrain is "fishing expedition," but it is just that, and particularly since we learned earlier this week in connection with the preliminary discussions for the Court-ordered mediation, which Liberty has opted to participate in, given its total lack of resources, that the PSC has yet to be even able to tell us which clean room was allegedly defective and what the theory of causation is.

So, all the more reason that the expansion of the original motion -- subpoena served upon Travelers is really inappropriate and should be quashed. It should not be enforced as the PSC is seeking to enforce it.

THE COURT: All right. Thank you.

Counsel for the PSC.

MR. LIPTON: Over here, your Honor. Marc Lipton on behalf of the PSC.

So, we are here to talk about two issues, and what I heard was that Travelers now has agreed to produce all

insurance policies that they have for Liberty, which today I learned for the first time are more than just the two that we talk about in the motion.

So, I would just point out to the Court that there wasn't a meet-and-confer process between December and today. So, eight weeks, thereabouts. And throughout that time we were told they would not produce those documents. To hear this morning for the first time that they will is great. I would ask the Court to enter an order requiring their production within five days, should be reasonable, I would think, but I -- as you can see, this whole process is getting dragged out and we would like that -- a deadline put in. So, good faith being what it is, I still want to have that deadline.

The second issue is the alleged overbreadth of our requests. I heard that counsel for Travelers now concedes that she could understand why we might want that information. And so, again, it sort of sounds like a concession that she's willing to produce it. I don't think there's a whole lot of detailed analysis that goes on here.

The second reason by Travelers terminated the policy was because supervision and monitoring the clean room construction could become a professional liability itself if constructed improperly, which are the allegations against Liberty in this case. We're not really looking for the

internal deliberations of Travelers. We are looking for the facts and circumstances that led to the cancellation that we know of and any other cancellations that apparently may have gone on that we don't know of. So, we want those documents.

When somebody comes to the Court and argues that a subpoena is overbroad or burdensome, they usually have an obligation to come forward with some evidence of that.

There's nothing here. There's no affidavit. There's no description of why it is too hard for Travelers to open its files, go on the computer, hit "Liberty" and print the documents.

And then as far as -- there's a couple of things they threw in there that I think are equally meritless. The mediation program is designed to -- and the order is designed to limit the PSC's responsibility and Liberty's responsibility to produce documents. It's got nothing to do with third parties. Liberty has a right to go after its own third parties through the process and give us notice and get records, just like we do. So, Travelers is not protected by that.

You know, Liberty's argument that they would be prejudiced by the production of this material is precisely the point and, as we learn in law school, prejudice is not a reason not to produce discoverable material. That's what we're looking for, is prejudicial information that gives us a

reason to pursue our claims against them.

So, you know, beyond that, I don't think I have a whole lot to add. I think this is a pretty simple motion and I would just request that the Court, if it needs to wait until it issues a written opinion, that it put a shorter timeline in the production of documents and if it's going to issue an opinion from the bench, that it give a short but reasonable time for Travelers to produce the information so that we can move forward.

THE COURT: All right. Anything further from Travelers or Liberty?

MS. LUCY: Yes, your Honor.

I am here today filling in for another attorney who handled this.

And, first of all, if Mr. Lipton formed the impression that I said that there were more than two policies, I did not intend to say that. I said there were various policies, I understood, over the timeframe. I'm not representing how many because I certainly don't know for sure, your Honor.

Secondly -- but I did talk about the 2005 through 2012.

Secondly, I spoke with Mr. Cullen before coming here this morning and he did tell me he had a conversation with PSC's counsel and did offer to produce the other policies. I

was not a party to that discussion. I cannot say if it happened. That's my understanding.

Thirdly, overbreadth, your Honor. The documents —
it is overbroad and there is a concern on that and trying to
determine what's related to and what's not related to is a
problem, and underwriting files are not all on a computer
where you can push a button. So, if that were the case, it
wouldn't be unduly burdensome to try to make sure we complied
with the order. So, that is an issue.

And I would ask that if the Court -- since, obviously, we are agreeing to produce the policies, just maybe give us a little more than five days, maybe ten days, I think that would be good, to make sure we have the complete policies, because policies need to be requested. It's usually a two-week timeframe, I believe, and to get a certified policy, that's usually what it takes.

With respect to documentation, I'd ask if the Court clearly -- if you're going to enter an order, clearly order that the documentation -- the additional documentation that we're to produce pertains to that cancellation, the 2010-2011 policy, so that we can be certain that we are in compliance with the order. Thank you.

THE COURT: All right. I'm going to take that under advisement, and we'll move on to the plaintiff fact sheets, and I'll hear from the PSC first. And it sounded as if the

parties were going to continue to negotiate these issues since the filing of the profile forms on this issue.

MR. STRANCH: Your Honor, we've reached an impasse on the plaintiff profile forms, the fact sheets, depending on how you want to characterize the document. We're kind of at that point.

There's a comedian in the South who speaks to legal communities and we're at the point where we need you to "shoot up here amongst us," your Honor, so that we can -- one of us can get some relief and we can move this case forward.

This is one of the stumbling blocks that's stopping us from moving this case into the discovery phase and we need to move that. *Granuflo* that was only sent here a couple of months ago, it's already taking depositions next week. We still don't have document productions. We need to move this case.

We've offered a profile form that we believe provides more information than is necessary to make Bellwether selections for cases that then undergo full discovery. So, this is not you have to pick this case and that case will be tried. This is just to pick a group of cases that will then undergo full discovery and then from that pool, the trial cases will be picked. And so, you don't need the same level of information, pick a case that will absolutely be tried.

As an example, in the *Granuflo* case, which is also

here in this district, their profile form is four pages, you know. It's simple. You don't need a lot -- you need enough census data to characterize the claims so that you can see is this a death case, is this an infection case, is this a fungal meningitis case or is this an exposure only slash fear case.

I think if the Court -- before I go into our plaintiff profile forms, does the Court have any specific questions about our forms that I could address that could speed this process?

THE COURT: I do. So, for example, I believe that the PSC does not have a question relating to loss of consortium. Or do I misunderstand this? I think they don't believe -- if I read the form correctly, that the plaintiffs' form does not ask for any identifying information about the spouse or family member, and I was wondering if there was a loss of consortium claim, why that would not be appropriate for being in the form.

MR. STRANCH: Your Honor, we do have questions about people's familial relationships, whether they have children, whether they have a spouse.

THE COURT: All right. It doesn't have any identifying information; is that correct? Or --

MR. STRANCH: It asks the name of your spouse, the date of your marriage, for each of your children list their names and ages. You know, it's -- there is some information

about it, but, more importantly, your Honor, complaints are already on file for each one of these people that detail those allegations, you know. And so, they say, I'm making a loss of consortium claim for, and then it explains it within the complaint. And so, that information is already out there.

One of the kind of issues we're having is a lot of this information is already available. One of the complaints that the defendants raise here are that we don't give them the last four digits of the Social Security number so that they can get records. Well, if you go look at the medical authorizations on there, when they sign it, they're supposed to fill in the last four of their Social.

There's a complaint that there's not a date of birth on the form. On each of the releases there is a place where you fill in, here's the date of birth of the person releasing the records so that the records can be found easily. So, the information is there. It just may not be in the form specifically where they want it.

And we're trying to lessen the burden because there's a lot of cases in the MDL. There's limited funds with most of these defendants. And, frankly, all 85 cases or 100 cases or 500 cases are probably not going to be tried at once. And so, instead of having people spend thousands of dollars and attorney's time and in fees and expenses, you know, trying to get this information, collecting it for medical records, it's

there. THE COURT: All right. And then perhaps I've misread this one as well, but it seemed to me that the plaintiffs did not want any questions about substance abuse; is that correct? MR. STRANCH: We do have questions that get at that issue. We ask, for example, have you ever been diagnosed with cirrhosis of the liver. THE COURT: Right, but that's rather far down the line --MR. STRANCH: Yes. THE COURT: -- in terms of alcohol abuse.

MR. STRANCH: Yes. We don't believe that the questions that they had proposed were necessary. We have questions about tobacco use and we ask about that, and we ask how long they've been using the tobacco products for that. We ask about the cirrhosis of the liver. We do not have a specific question that says, How many drinks do you have a day? How many drinks do you have a week? Because, frankly, there's no scientific evidence that's been put forward to us that would make that relevant.

We've asked -- and we've just been told, Well, everybody knows alcohol use is important. And that's not sufficient to do it. They need to provide some sort of information that makes it relevance. So, if a person drinks one glass of wine every day with dinner, they need to show how

that's related to causation or how that's related to damages, and that's not been done.

The reason we left cirrhosis in, your Honor, is to catch those people that had already progressed to a point where they've done basically irreversible damage to their bodies through alcohol consumption or potentially through other means that have caused it, but that's the key there. And so, that's what you need to know because that's the point at which you have the significantly-shortened life span or other things that would change the actuarial tables for you. So, that's why we've proposed that.

And, additionally, your Honor, if there is a concern with the alcohol use such that it would affect their medical health, it's going to be within the medical records, because we're giving them all of the medical records so they can look through it.

THE COURT: All right. And then -- but I believe in terms of the mental health treatment, which is perhaps another area where that may show up, if I remember correctly, the PSC form does not require the plaintiffs to provide dates of treatment or the treatment provider's address.

MR. STRANCH: That is incorrect. What we've said is if you're raising a claim for emotional distress or any sorts of mental healthy damages and you have sought medical treatment for it -- and we say, for example, with a therapist,

a psychiatrist, a hospital, an in-patient facility, just as an example, not as a limitation -- then you have to fill out a separate form that discloses that information, list who the providers are so they can go get it.

Where we have drawn a line in the sand, your Honor, is we've said sexual abuse records are not appropriate and we're not going to agree to turn those over for every single person, but what we're willing to do is if they want -- if they can make a showing that they're somehow relevant to any single plaintiff's case, we're willing to consider that showing and to meet and confer with them on that, but we believe that is highly, highly intrusive with no relevancy whatsoever at this stage for Bellwether production, your Honor, and we believe it's highly unlikely that it would ever be appropriate in the case, but we've left the door open to consider that on a case-by-case basis.

THE COURT: All right. And then I might -- it's a lot of the same arguments, so I think I'll also give you the questions now for the releases.

MR. STRANCH: Sure.

THE COURT: So, with respect to the employment releases, it's my understanding that the plaintiffs' release does not include worker's compensation claims; is that right?

MR. STRANCH: Your Honor, what we've said is for the employment records, any and all personnel records, employment

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applications, job descriptions, payroll, salary records,
letters of commendation, discipline, performance evaluations,
and other things, there is a separate disability insurance
award that would go through there, and we've also said in the
form provide a list of any awards that you received for
worker's compensation, so that they would know what the awards
were and what the disability was.
         THE COURT: But the release wouldn't authorize any
communications?
         MR. STRANCH: Yes.
                             It's -- Exhibit 7, I believe,
your Honor, is authorization for release of worker's
compensation awards.
         THE COURT: And that one is limited -- right. So,
you have a release to worker's compensation, but not for the
employer's records on worker's compensation; is that right?
         MR. STRANCH: The release for the award -- for the
worker's compensation award, this is to whoever the award was
against so that they can release those records.
         THE COURT: And that one is only for permanent total
disability or permanent partial disability; is that right?
         MR. STRANCH: That is correct, your Honor.
         THE COURT: Why is it limited in that way?
         MR. STRANCH: Well, for example, your Honor, in the
worker's compensation scheme, if I fall off a ladder and break
my arm and I heal completely and have no permanent disability
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1 from it, it's not relevant to anything. There's no relevance 2 whatsoever. If that happened in 1985, why do we need that? 3 It doesn't help with the Bellwether selection at all. What does help and what we do think is relevant and 4 5 what we have agreed upon is if a court or -- either through 6 settlement or through trial has found that you are 15 percent 7 permanently disabled or 100 percent permanently disabled, we 8 think that's relevant to your damages and we think it's also 9 relevant potentially to Bellwether selection process, but if 10 you had no permanent disability or partial permanent 11 disability; in other words, it resolved itself completely, then we don't think there's any relevancy whatsoever. 12 13 THE COURT: And I don't believe the plaintiffs have 14 put forward a separate insurance authorization. 15 MR. STRANCH: Insurance? 16 THE COURT: Insurance company authorization. 17 MR. STRANCH: For their medical records? 18 THE COURT: Yes. 19 MR. STRANCH: We've said that they can get all the 20 records from the providers, which would include the insurance billing information --21 22 THE COURT: Right. So, for example, the Tennessee 23 and St. Thomas groups, I think it's Tab E, have a separate 24 insurance authorization, and there's no such separate 25 insurance authorization from the plaintiffs.

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               MR. STRANCH: Your Honor, we don't believe that
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      that's necessary.
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               THE COURT: So, that's my question. Why?
               MR. STRANCH: We don't believe that's necessary for
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      the Bellwether selection process because they're already going
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      to have all those records themselves. They're going to have
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      the records saying --
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               THE COURT: The individual plaintiffs will have those
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      records?
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               MR. STRANCH: No. The defendants will have those
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      records. St. Thomas billed the insurance carriers and were
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      paid by it. So, they will have the records to show them what
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      was done. In Tennessee when you file a notice --
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               THE COURT: But they'll only have the records for
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      their treatment.
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               MR. STRANCH: Well -- I'm sorry, your Honor, let me
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      back up.
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               In Tennessee when you file one of these claims, you
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      have to provide a notice beforehand which includes medical
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      records, releases for all of your treatment that you received
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      as a result of the injury.
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               THE COURT: But don't we have more than just
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      Tennessee plaintiffs?
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               MR. STRANCH: Yes, we do, your Honor. We do have
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      more than that. And most states, as I understand it, require
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      some sort of similar process, not all of them, but you'll
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      get --
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               THE COURT: I could be wrong. I don't think that's
      required in Massachusetts.
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               MR. STRANCH: Okay. But when they get the records
      from the hospital where the person received the treatment,
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 7
      billing records are going to be a part of that which are going
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      to include the insurance records. And so, they will get what
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      the insurance company was billed and what the insurance
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      company paid for on it already.
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               MR. GASTEL: Your Honor, Ben Gastel on behalf of the
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      plaintiffs.
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               There might be a disconnect here. Are you talking
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      about medical records insurance or disability insurance?
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               THE COURT: Medical records insurance.
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               MR. GASTEL: Okay. Thank you, your Honor.
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               THE COURT: All right. So, is there anything else
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      you would like to add or I can move on to my questions to St.
19
      Thomas and Tennessee?
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               MR. STRANCH: Unless you have anything else to ask,
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      your Honor, I'm happy to rest subject to rebuttal.
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               THE COURT: All right. So, who is going to speak for
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      -- do you want to move up to the table?
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               MS. KELLY: Counsel on the phone are going to handle
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      this.
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               MS. GREER: Your Honor, we're by phone, but I believe
      -- this is Marcy Greer on behalf of the St. Thomas entities.
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      Can you hear me okay?
               THE COURT: Yes.
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               MS. GREER: And I believe that Chris Tardio is also
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      on the phone.
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               (Discussion off the record at the bench.)
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               THE COURT: And the court reporter has asked if Marcy
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      Greer could speak up.
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               MS. GREER: Okay. Is this better? I apologize, your
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      Honor. We tried to be there, but our flights were cancelled.
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               THE COURT: All right. Go ahead.
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              MS. GREER: Can you hear me now?
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               THE COURT: Yes.
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               MS. GREER: Okay. Good.
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               THE COURT: Did you want to say something before?
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      have a number of specific questions.
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               MS. GREER: If I could just briefly touch on a couple
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      of overarching issues that came up in Mr. Stranch's argument.
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               The first is that the purpose of the fact sheet, as
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      we have made clear in our papers, is not just for selecting
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      Bellwether. It's also for obtaining these records before they
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      get lost forever. The fact sheet and the authorization kind
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      of go hand in glove because the fact sheet gives us the
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      information so that we can make sure we've got the medical
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records. That is necessary because, yes, you know, we agree that not all these cases are going to go to trial, but some of them are and none of us sitting here today know which cases those are, and that's why it's important for us to gather the medical records.

The issue is not relevance. They keep saying we have to prove it's relevant somehow to the Bellwether issue. There is no caselaw to support that and that's not the test.

There's really not much of a question. Every bit of information that we're requesting on our proposed fact sheet would be relevant and would be discoverable if this were a single-plaintiff case, but what they're trying to do is basically usurp the role of the Court by deciding what's relevant in advance and tying it to this limited understanding of the Bellwether process. Again, we're trying to make sure that both functions of the fact sheet are fulfilled here and that's why we've asked the questions.

We have made significant progress in cutting it down. As the Court can see from our Exhibit M, we've gone back to the drawing board and tried to give up on as much as we can to streamline this process and get it to the next level, but the records are very important and we have to have the background information so that we can find it. They say things like addresses going back ten years are not relevant. Well, they are because that's how we make sure we get the records. This

is our one chance to have these people fill out a form.

And, again, they talk about all the attorney time and all the difficulty here. These are forms that people are going to know off the top of their head. I mean, I think most people know their Social Security number, and going to -- who they've seen going to the doctor, et cetera. They know whether they've been diagnosed with cirrhosis or not. It's a simple check yes or no or I don't know in cases.

So, they're not having to compile any of these records, just a very few at the end that we've asked for, and we can talk about that later, but the point is, is that they sit down and fill out this form just like they would at the doctor's office for a new-patient visit, and then we go get the records, and that burden on them to ask a few extra questions to help us get to the point where we can find out the information we need, we submit, is not significant in light of the importance of gathering these documents, because the reality is that trials are going to be taking place if this plays out like a lot of MDLs have for years to come and if we haven't gathered the records now -- what if we don't get all the records for a certain person. Then six years now or five years from now or heaven forbids later, those records may be gone, not available.

So, that's why we have asked the questions. We've tried to be very fair and faithful to fact sheets that were

used before. We've provided the Court with a lot of quidance, and I'm happy to answer specific questions, but I did want to give the Court the benefit of that overview.

> THE COURT: All right. Thank you.

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So, why are sexual abuse records relevant at all and, in particular, for this stage of the proceedings?

MS. GREER: Your Honor, we are prepared to give up on sexual abuse records. Our concern is that it was presented in an extreme example, but it was used by PSC to argue that we shouldn't get psychological records unless there was treatment for a psychological issue.

In the real world, that doesn't always happen. the real world, there may be psychiatric or psychological issues that appear in marital counseling and under their version, we wouldn't get those records because the person went in for marital counseling and not psychological or psychiatric treatment. That's our concern.

If they want to carve out for just sexual abuse records, we can do that, but we don't want the carve-out to be so broad and it was always joined with the rest of the records, that we fail to get psychological records, because there are a lot of patients here who are claiming fear claim and if their claim is solely exposure and fear of contracting meningitis, then we need to get those psychological records. They're going to be very important.

THE COURT: And then the family medical history questions also seemed quite detailed and while I could understand a case being made for relevance, again, my question is why at this stage?

MS. GREER: Well, the issue here is acuity. They talked about things like product I.D. I don't think those are going to be big issues in this case for obvious reasons. These are prescription drugs, et cetera, but things like acuity are very compelling in this case. Why -- a lot of people were injected with these steroids, yet only a few ended up getting sick. Why is that? There's no pattern that we've been able to see.

And so, we are asking for history really on things like historic family information that you would know. You know, did your father have heart disease? I mean, that's really all we're asking. And autoimmune and immunity are the disorders we think will play a significant role in this. And so, that's the function of those questions.

If you go to the doctor's office, those are on every new patient form. Have you ever had a history of, list all these things in your family.

THE COURT: And moving on to the authorizations. Why do you need authorizations for educational records?

MS. GREER: We typically get those at this point.

Again, this is the function not for purposes solely of the

Bellwether, but for purposes of gathering the records so that we have them. This is not an MDL with thousands or millions of plaintiffs. This is a little over 100 for the St. Thomas entities, and right now we're the active cases. There's no reason not to go gather these records now if there's no burden on the plaintiff. All they have to do is sign the form, and they have put it at issue by bringing the claim. Again, if this were a single-plaintiff case, we wouldn't even be having this discussion. They would just have to sign them.

THE COURT: And I don't believe the defendants put in a counter tax return release. I believe the plaintiffs used the IRS form. Is there -- I think there may be some dispute as to the timeframe, but no one is objecting to the form; is that correct?

MS. GREER: We are not. And, your Honor, that was an oversight. One of our filings did, in fact, have the tax form and I think it just got left off of this one, but we agree that we do need the tax form and we're fine with all of that subject to time.

THE COURT: All right. Anything else?

MS. GREER: That's all I have. I think Mr. Tardio has some comments.

MR. TARDIO Your Honor, this is Chris Tardio with Nashville. I represent St. Thomas Outpatient Neurological Center and various other Tennessee defendants.

We filed a proposed fact sheet which is similar to the one St. Thomas filed, but with some -- I think it strikes more of a middle ground on some of the specific questions.

I don't have anything to add to what Ms. Greer said about the relevance at this stage of the family medical history information, and I'm also willing to build in a carve-out for sexual abuse records. So, I don't have anything substantive to add to what Ms. Greer said other than to inform the Court that overall on some of these specific issues, like substance abuse, we spent a good bit of time trying to build a form that struck a middle ground between the plaintiffs' form and the St. Thomas form and took into account both the PSC's concerns with the intrusiveness of the questions and our need for the information at this stage of the proceedings.

THE COURT: All right. Thank you.

Anything further from the plaintiffs on this issue?

MR. STRANCH: Yes, your Honor. I have a couple of things that I want would like to talk about briefly.

We've heard today for the first time throughout the 70 odd days that we've been negotiating over this that the real reason is an attempt to preserve records.

Your Honor, I think that should ring false, you know, because if there's a real concern about preserving records, then, at a minimum, plaintiffs should be getting records that we've been requesting since October from the defendants.

Secondarily, there are statutory obligations on hospitals and clinics to maintain records. And so, hospitals don't just throw them away if they don't see a patient for 30 days or 40 days or 60 days. In fact, if you talk to any physician, they're going to tell you one of the most important things they can have with their patients is that detailed history that goes back for years and years, and they build it up so that they can treat the patients. The records are there. They're not going to be destroyed. And so, I think that should ring hollow and I think it's a waste of everyone's time and effort at this point in the Bellwether selection process.

And one issue we still do not know, despite this

Court's order to respond to document requests through the

subpoenas that were served earlier, we still don't know if the

entities opposing this have wasting policies that are taking

money away from the potential plaintiffs at the end of the

day. We don't know that. And so, this could be literally

taking money away from the plaintiffs and putting it into the

defense lawyers' pockets.

Secondly, your Honor, you heard that the family medical conditions are necessary to determine causation because some people may be more susceptible to infections through MPA. I cannot for the life of me see how my grandfather's HIV status or my children's HIV status has any

bearing on whether I contract a disease when I receive a shot or not. There's no relevance whatsoever.

We have agreed to produce the records as it relates to the person who was injured. Do they have an autoimmune disorder? Do they have HIV? Do they have AIDS? We've agreed to produce those. That's what's needed to determine causation and whether they may be more susceptible or less susceptible. Siblings' records and grandparents' records, parents' records, children's records, all a complete fishing expedition, no relevance to causation whatsoever, your Honor, and it's incredibly burdensome and it invades the privacy of those individuals.

In fact, looking through the law, we believe we are prohibited from providing it under many states' laws and there's also a problem under HIPAA for the parents to do it on behalf of the children or for grandparents or others that they may hold medical power of authorities for because they may be violated HIPAA by providing that --

THE COURT: Actually, you've reminded me of a question. I had understood from your submission that you want the medical records to go to a HIPAA-compliant vendor. And then I believe the defendants suggested in some way that you were going to screen them first, but I can ask the defendants after this, but my understanding, at least with the medical records, is that you want them to go to the HIPAA-compliant

1 vendor. 2 MR. STRANCH: Your Honor, we have asked that they go 3 to the HIPAA-compliant vendor and we would offer to screen them before they went to make sure that anything that was in 4 5 there that was not responsive, for example, any sexual abuse or any other things would be removed from that. We've 6 7 actually worked through that issue. 8 THE COURT: Okay. 9 MR. STRANCH: And so, we don't believe that's a 10 problem anymore. 11 THE COURT: All right. Thank you. 12 Anything else? Yes. I believe the gentleman behind 13 you wanted to speak as well. 14 MR. ZAMORA: I'll wait for Mr. Stranch to complete. 15 MR. STRANCH: Okay. 16 MS. GREER: Your Honor, may we be heard? 17 Yes. What I would like to do first is THE COURT: 18 why don't we finish up with the PSC and then I'll hear from 19 the other gentleman in the courtroom and then I'll come back 20 to you. 21 MR. STRANCH: And the one last thing I wanted to hit, 22 your Honor, was there was a suggestion that we have not raised 23 an issue with the relevance -- ultimate relevance of any of 24 the information that they've requested in the plaintiff fact 25 sheets.

I think we've demonstrated here today that there are, in fact, things that we do object to ultimately coming into the record or being discoverable at any point in the litigation, like the family medical histories, you know. We think, for example, that if you're not making a lost wage claim, they don't need to get your employment information. They don't need any of that.

So, we do think that there are some issues like that. And the way we've dealt with those, your Honor, is we've said, in an effort of compromise, we're not going to give it to you now, but once you have the information from that person, if you believe it's relevant and can make a showing, we would be happy to meet and confer with you and discuss it and consider it by on a case-by-case basis and if it's relevant, we'll give it to you if we agree and if not, then it's a discrete issue that can be put to the Court quickly and simply.

THE COURT: Thank you. Yes.

MR. ZAMORA: Your Honor, Mark Zamora for the plaintiffs' steering committee.

Your Honor had asked a few questions early on in the process about substance abuse. And so, I was referring to Ms. Greer's submission, Questions 41, 42, 43, which I think goes to the heart of use, and I think your Honor aptly noted the critical distinction that we're going to have if questions go to this in any fact sheet that's approved by the Court.

What's instructive for us, if you look at the submissions from the defendants, they rely upon the Yaz filing as, in essence, the basis for those types of questions.

So, when you look at the product itself, what's important to recognize in the Yaz litigation, for example, smoking was a key factor that related to a number of the questions of injury involved in that case. Here we don't have that. Even if you presume for the sake of our discovery that there is some relevance to it, you'll note in the Yaz case, it was limited by time to three years of smoking.

You then discuss alcohol abuse in Yaz which may have had a compounding effect on clotting or DVDs in that case, which was limited to one year of use, but when you look at defendants' own filings, your Honor, and you especially look at the study that was performed that was written up on fungal meningitis and how rare it is of a human pathogen, nothing in that science that they submitted suggests any reason or basis to ask for this type of information.

And there's something that's really important for your Honor to -- I think you picked up on the nuisance -- was of use. They asked for use. Not only do they ask for use, they go much further than any filing on a case that is similar to this by asking for ten years.

So, if there is to be some type of revision or compromise in a sense to get to the truth of the plaintiffs'

case, I think you aptly noted by saying "of use." And so, the question of simple use nine or ten years ago will lead to nothing other than folks saying why in the world are they asking for -- explain how -- why I had a glass of wine nine years ago.

The second component, your Honor, which is really instructive -- and I'm done after this -- asking for the medical records. There's an old saying that everything is related to everything.

When you look at the fungal meningitis study that was submitted, your Honor, most of these cases the mean age is 69. So, they're asking for high school records going back 45 to 50 years, and I think you can predict what's going to happen when those requests are made. We don't have them. So, we'll be back stuck in the muck and the mire asking for 45-year-old educational records.

Simply asking for them without a showing of saying anything more than, We need them, is not sufficient in the context of this litigation and the injuries that are alleged.

And there's more than just a few. There's more than 65 -- I think Ms. Greer said only a few got sick, and I think I speak for all the defendants' lawyers in this room. When there are more than 60 deaths and more than 700 injuries, it's more than just a few people got sick. So, I think you judge the submissions by their relevancy to fill the pool for

Bellwether selection.

THE COURT: Thank you.

Counsel on the phone, anything further?

MS. GREER: Yes, your Honor.

First of all, with the issue of preservation and the role of fact sheet in gathering records, we have raised this in several hearings and it's been in both of our papers relevant to this, that there are twin purposes of the fact sheet and that the PSC has focused on solely the Bellwether, but this does not come to them by surprise.

With respect to records, we're only seeking to go back ten years. We're not seeking to go back in time ad infinitum, but we think ten years is really important, especially as to the medical records, because you need that information to show trending and, as the Court can see in all the fact sheets that we submitted from other cases, they go back ten years, some cases 20, and some for life, but we've asked for ten, which we think is very reasonable under the circumstances.

The decision -- the issue of preservation and what the law provides for hospitals, that's not the issue. We've got our records and they have been preserved. The issue is the treaters, the physicians who are not subject to the same records.

We're trying to get a wholistic health history. They

want to keep us to just the records relating to the injections and the subsequent treatment, and we need a more complete health history to be able to evaluate these plaintiffs for Bellwether and also to make sure that the records are preserved if that case ends up being the one that goes to trial.

With respect to employment records, we've tried to make it clear repeatedly that we are not seeking employment records unless the plaintiff has put that issue into the lawsuit by seeking claims under that. It's simply a red herring for them to keep bringing it up.

As to the substance abuse issue, we are looking for abuse, but we're also looking for heavy use. They said that there's no science to support heavy use of alcohol. Well, the FDA is requiring warnings on Tylenol and Motrin that if you drink more than three alcoholic drinks a day, you may be subject to liver damage. So, there is reason to ask those questions.

And it's not limited to just the Yaz litigation. Every single fact sheet that we submitted asks questions about tobacco use, not just if they're using it currently, but if they have used it in the past. If someone smoked for 30 years and then quit two years ago, that's relevant.

I think the Court should be aware that many of these patients have strokes as part of the meningitis complications

and strokes have many, many different etiologies and we need to explore that to understand why some of these patients got sick.

I did not mean to suggest that there were only a few patients who got sick. I was suggesting only that of the percentage of patients who were exposed to these steroids, not all of them got sick. A smaller percentage got sick. And so, we want to find out what it is that caused those patients to get sick and not others. Some of that is outlined in the New England Medical Journal article that we submitted to you, but they agree that this is something that needs to be studied further.

As to the repository, there are two issues on that.

One is access and one is dollars, because the access issue in our mind is by far the most important. I'm not sure where we have resolved this. I certainly haven't seen anything in writing that would suggest that the PSC is not going to try to screen these documents ahead of time to determine what's relevant. That was said in a -- in a meet-and-confer, but I don't have anything to back it up.

There's just no precedent that the PSC would get to be the gatekeepers here and make the relevancy determinations that are for this Court to make.

And then there's also the issue of dollars, that they want to charge money for us to access this repository once the

records are compiled, and we're simply trying to say there's a way to do it. It's been done in hundreds, if not thousands, if not millions of cases. You send the medical authorization to the third-party healthcare provider and they produce the record. If there is an issue, the other side can object and we deal with it at that point on a case-by-case basis.

Again, we're talking right now about a little over 100 plaintiffs, which is a lot of plaintiffs, but it's by no means the thousands of plaintiffs that were implicated in the Yaz litigation and some of these other cases where they have used more truncated forms.

THE COURT: All right. Anyone else on the phone wish to speak?

MR. TARDIO Your Honor, this is Chris Tardio again on behalf of the Tennessee defendants, and I won't address all the points that have been raised at this point or rehash any of the arguments because it's not worth the Court's time.

However, I do want to address specifically two points. One is substance abuse, which seems to have been a focus thus far of our discussion, and I respectfully direct the Court to our proposed form, 41 through 43, or Question 41 through 43, where we attempted to weed out occasional users of alcohol and attempted to ask such that only identifies abusers. So, we did try to strike a middle ground on that question to lessen the intrusion on the plaintiffs filling out

the form.

The second point I did want to make on the loss of consortium question, which we included in our form, and I believe it's a perfect illustration of what we tried to do, spending hours literally on our form, simplifying the questions to make it such that the burden on the person completing the form, not the lawyer, but the person, the plaintiff who is actually going to be completing the form, the burden is low. It's a simple question that can be answered from memory, but the yield of information is high. So, we've tried to balance throughout the form the burden on the plaintiff completing the form with the potential to yield important information to select representative cases and, probably more importantly, to weed out non-representative cases.

THE COURT: All right. Thank you. So, I'll take this issue under advisement. Yes.

MS. PARKER: If I may, your Honor. I just have two pieces of information that I thought may be helpful to the Court.

The first is that reference has been made to a HIPPA-compliant vendor, and just to let the Court know, that earlier in this litigation the PSC retained an established HIPPA-complaint repository. The vendor there is Omni Rust. That was established by a court order earlier in this case and

that vendor is -- just to give context for it, that's an existing vendor that is already performing functions related to this litigation.

And the second is to let the Court know that the PSC has filed a discovery and trial plan, proposed only, that contemplates a trial of the St. Thomas action in the spring of 2015 and that proposed -- that's Dockets No. 837 and 838 in the MDL docket. That proposed schedule contemplates a relatively quick resolution of this and other discovery issues so that the parties may move forward, and I share that with your Honor only because I know sometimes it's helpful to have a larger context for how these discovery battles fit into the litigation plan.

THE COURT: All right. Thank you.

And in accordance with that, I also have -- what I had understood Judge Saylor to refer to me was the determination of the content of the plaintiff fact sheets, authorizations to release records and protective orders. I don't see -- and perhaps I missed that there are any protective order requests. I know there have been some already issued in the case.

MR. STRANCH: Your Honor, there was a dispute over the protective order. There was an attempt to modify that.

Judge Saylor dealt with that by order shortly after the referral to this Court. And so, we believe that that issue

1 has been resolved. 2 THE COURT: All right. And then the other issues 3 that I believe only the plaintiff addressed, which I'm not clear are squarely before me, are the deposition protocol and 4 5 then also the protocol for electronic discovery. MS. PARKER: Yes, your Honor. So, the plaintiffs' 6 7 steering committee had provided drafts of the agreement and 8 attempted to meet and confer on them with the defendants, 9 including the St. Thomas defendants. 10 We included our proposed versions of these in our 11 latest submission before this Court. Admitted entry for last 12 month's status conference as entered today we think gives us 13 further quidance that we should propose those to the Court 14 generally in the form of a motion rather than having included 15 them here. So, our intention is to file a motion for entry of 16 the ESI protocol and deposition protocol. 17 THE COURT: So, I will not ask you any questions 18 about them. 19 MS. PARKER: We are prepared to discuss them if your 20 Honor would like to, but that was our understanding how to 21 move forward. 22 THE COURT: All right. Is there anything else from

 $$\operatorname{MR.}$  STRANCH: The only thing we would say, your Honor, is --

the plaintiffs' side at this point?

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               THE COURT: You just need to pull the microphone.
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               MR. STRANCH: The only last thing we would say is on
 3
      the plaintiff profile forms, you know, the Granuflo case we
 4
      think would be instructive for the Court to look at. We've
      attached that to ours. We've also referenced it. That's in
 5
 6
      this district. We believe the Court should take a look at
 7
      that. In particular, the releases there are limited to three
 8
      years instead of the longer period.
 9
               THE COURT: All right. Any one else in the courtroom
10
      wish to speak to anything?
11
               (No response.)
12
               THE COURT: Anyone on the phone?
13
               (No response.)
14
               THE COURT: All right. Thank you very much.
15
               COURTROOM DEPUTY CLERK YORK: All rise. Court is in
16
      recess.
17
               (Adjourned, 11:25 a.m.)
18
19
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21
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23
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25
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## C E R T I F I C A T EI, Catherine A. Handel, Official Court Reporter of the United States District Court, do hereby certify that the foregoing transcript, from Page 1 to Page 51, constitutes to the best of my skill and ability a true and accurate transcription of my stenotype notes taken in the matter of Civil Action No. 13-02419-FDS, In Re: New England Compounding Pharmacy Cases Litigation February 9, 2014 /s/Catherine A. Handel Catherine A. Handel RPR-CM, CRR Date